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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/656,973	09/05/2003	Meir Rosenberg	022719-0047	8809

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EXAMINER	
DEAK, LESLIE R	

ART UNIT	PAPER NUMBER
3761	

NOTIFICATION DATE	DELIVERY MODE
12/20/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docket@nutter.com

Office Action Summary	Application No.	Applicant(s)	
	10/656,973	ROSENBERG, MEIR	
	Examiner	Art Unit	
	Leslie R. Deak	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9 and 13-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *05 September 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 30 October 2007 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-4, 6, 7, 9, 13-15, and 17-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over US2003/0032915 A1 to Saul in view of US 6,533,733 to Ericson et al.

In the specification and figures, Saul discloses the invention substantially as claimed by applicant. With regard to claims 1, 9, 17, Saul discloses a method and device for volumetric removal of CSF from a hydrocephalus patient with an implantable, controllable shunt system. Saul discloses a ventricular catheter 12 and peritoneal catheter 14 that are connected via a flow control valve 48. The catheters operate to

shunt CSF from the brain ventricle to the peritoneal cavity (see paragraph 0034). The system is operated via controller 44 that operates the movement of the valve 48 with power from source 46 based on input from a sensor such as a pressure transducer 40 that is located on the distal end of catheter 12, within the ventricle (see paragraph 0034).

Saul fails to disclose that an external system controller communicates with the shunt and valve system remotely via telemetry. However, Ericson discloses a method and device for monitoring and shunting cerebrospinal fluid that comprises a transmitter 15 implanted within the patient that communicates with receiving unit 44 of an external telemetry system to enable remote energizing, monitoring, and control of the implant (see column 3, lines 5-10, 35-38, 65-67). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to add an external controller that communicates via telemetry as disclosed by Ericson to the cerebrospinal shunt system disclosed by Saul in order to enable remote monitoring and control, as taught by Ericson.

With regard to claims 2-4, 6, 7, 19-23, Saul discloses that when CSF fluid drainage is being controlled by volume, sensing devices in the shunt (such as pressure sensor 40) send signals to the controller 44, which adjusts the valve between an open and closed position based on the signals sent to the controller from the sensor (see paragraphs 0035-0037). The sensor reports the volume of flow through the valve, and once the desired volume has been reached (which the controller must determine by comparing the measured value to a desired value), the controller sends an electrical

control signal to the valve, adjusting the resistance of the valve to open (decreased resistance) or closed (increased resistance) in order to continue or halt fluid flow (see paragraphs 0035-0037).

With regard to claims 13-15, Saul specifically discloses that his apparatus and method are particularly intended for patients who experience hydrocephalus with "normal" intracranial pressures, i.e, normal pressure hydrocephalus (see paragraph 009).

With regard to claim 18, sensor 40 is coupled to controller 44, which is coupled to valve 48, meeting the limitations of the claim.

With regard to claims 24-25, Ericson discloses that the sensors 11 of the shunt may comprise multiple pressure transducers (see column 3, lines 40-43). Therefore, it would have been obvious to one having ordinary skill in the art to provide multiple sensors as disclosed by Ericson, since it has been held that the mere duplication of the essential working parts of a device found in the prior art involves only routine skill in the art. See MPEP 2144.04(VI)(B).

With regard to claim 26, Saul fails to disclose that the valve is configured for implantation in the peritoneal cavity of the patient. Absent any showing of new or unexpected results of such a change in the location of the valve, it would have been obvious to one having ordinary skill in the art at the time the invention was made to place the valve in the peritoneal cavity, since it has been held that rearranging parts of an invention involves only routine skill in the art. See MPEP 2144.04.

4. Claims 5, 8, 16, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2003/0032915 A1 to Saul in view of US 6,533,733 to Ericson, further in view of US 2003/0004495 A1 to Saul.

In the specification and figures, Saul '915 and Ericson disclose the method substantially as claimed by applicant with the exception of repeating the resistance adjustment procedure at proscribed time intervals.

Saul '495 discloses a method and device for treating normal pressure hydrocephalus that comprises the steps of sensing a patient parameter, and then adjusting the opening pressure of a shunt valve with a controller based on patient conditions (see paragraphs 0019-0027).

With regard to claims 5, 8, and 16, the procedure disclosed by Saul '495 may be repeated, if desired, a set number of times per day, with the time between treatments set to allow the CSF to drain from a reservoir, allowing the patient to adjust to the current resistance of the valve, until a total desired volume of CSF is removed from the ventricular space, in order to prevent CSF leakage (see paragraph 27).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to repeat the adjustment procedure suggested by Saul '915 and Ericson multiple times, as disclosed by Saul '495, in order to prevent CSF leakage, as taught by Saul '495.

With regard to claim 27, the prior art discloses the device as claimed with the exception of a timed shut-off mechanism. Saul 495 discloses that his device may be controlled by a timer or programmable controller in order to control the valve based on a

predetermined time schedule in order to prevent overdrainage of CSF from the patient during a single time period (see paragraph 0027). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to add an automatic shutoff to the CSF shunt system in order to prevent overdrainage of CSF from a patient during a particular time period.

Response to Arguments

5. Applicant's arguments filed 30 October 2007 have been fully considered but they are not persuasive.

6. Applicant argues that one of ordinary skill in the art would not have been motivated to combine the Saul '915 reference with the Ericson reference, since the method and apparatus disclosed by Saul continuously monitors intracranial pressure and adjusts the valve accordingly, while Ericson discloses an external controller that is selectively operable to control the shunting system. Examiner respectfully disagrees.

First, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

In the instant case, the prior art teaches the steps of monitoring and controlling the valve based on measured fluid pressure that may be performed continuously as

disclosed by Saul or upon the performance of an energizing step as disclosed by Ericson.

Second, it has been held that broadly providing an automatic or mechanical means to replace a manual activity which accomplished the same result is not sufficient to distinguish over the prior art. See MPEP 2144.04(III). In the instant case, applicant claims a manual means that accomplishes the same result as a previously disclosed automatic activity. While the courts have not specifically held that such a conversion from automatic to manual activity is obvious, the court seems to suggest that merely moving between an automated and manual activity suggested in the prior art fails to provide a patentably distinct invention. Accordingly, it is the position of the Examiner that applicant's claims drawn to the manual steps of energizing, detecting, comparing, determining, and adjusting are unpatentable over the combination of Saul and Ericson which suggest the automatic performance of the steps claimed by applicant.

Third, applicant's claimed step of energizing the shunt system with the controller may occur at any time in the implantation and use of the shunt system, such as at the time of implantation. Accordingly, the Saul device is capable of being energized, or turned on, at the time of implantation, and then detecting, comparing, determining, and adjusting as claimed by applicant.

7. Applicant argues that the combination of the Saul and Ericson references do not yield predictable results, since the combination does not produce a device in which each element performs the same function as it did separately. Applicant contends that in the combination proposed by Examiner, the Saul device would no longer be pre-

programmed to automatically operate the shunt system, since the instantly claimed method requires the device to be manually energized.

First, applicant does not actually claim a manual energization process, and it is the position of the Examiner that the energization step may occur at the time of implantation.

Second, Saul discloses that the controller 44 may be programmed to operate the valve based on a variety of algorithms. Such a statement indicates that the controller may be programmed to await a signal from an external device (as taught by Ericson) before beginning the steps of detecting, comparing, determining, and adjusting.

Accordingly, it is the position of the Examiner that the combination of Saul and Ericson yields predictable results, since each element in the combination is capable of functioning in the same manner as it did independently.

8. Applicant argues that the combination of Saul and Ericson renders the Saul apparatus unsatisfactory for its intended purpose.

Saul discloses that the controller 44 may be programmed to operate the valve based on a variety of algorithms. Such a statement indicates that the controller may be programmed to await a signal from an external device (as taught by Ericson) before beginning the steps of detecting, comparing, determining, and adjusting. Applicant argues that "no person having ordinary skill in the art would be motivated to modify a method and device aimed at continuous, automatic op"ration to include the intervening step of energizing." Applicant does not specifically claim an "intervening" energizing step—the energizing step may be performed at the time of implantation in order to make

the device operable. It would most definitely be within the skill of a worker in the art to take a step that turns the device on, rendering it operable for its intended purpose. Accordingly, it is the position of the Examiner that the combination proposed by the Examiner does not render either device unsuitable for its intended purpose.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on Monday - Friday, 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Leslie R. Deak
Patent Examiner
Art Unit 3761
13 December 2007